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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,714	07/21/2003	Paul S. Keim	112624.00085 ORD	1368

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,714

Applicant(s)

KEIM ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28May2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 1 and 5 is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/4/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Restriction, received 28May2004, is acknowledged. Applicants elect, without traverse, Invention I, claims 1-10, drawn to nucleic acid, classified in class 536, subclass 24.32. Claims 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
2. Claims 1-10 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities:
Page 1, lines 25 and 30, the M. should be italicized,
Page 2, line 9, the M. should be italicized,
Page 4, line 26, there should be a comma after "and 8",
Page 7, line 1, *tuberculosi* should be *tuberculosum*,
Page 15, Table 5, there is no right side line on the table, inferring that the table is incomplete. If matter has been left off, adding matter may be considered "new matter", unless the information is presented elsewhere. Also, it is recommended that the column "IS6110 Pattern" be presented as a figure to preclude any problems with reproduction of the patterns,
Pages 18 and 20-25 are objected to because they contain an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
A listing of references beginning with number 13 has not been found in the application.
Pages 28 and 29 have not been found in the application, please advise,
Appropriate correction is required.

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Page 33, line 4, *strains* should not be italicized.

Sequence Identifiers

4. M.P.E.P. §2422.03, paragraph 9 recites:

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

Pages 20-26 contain amplicon sequences without the required sequence identifier.

Claim Objections

5. Claim 5 is objected to because of the following informality: *Mycobacterium tuberculosis* should be italicized to be uniform with the other claims. Appropriate correction is required.
6. Claim 1 is objected to because of the following informality: the listing of the group sometimes uses a comma and sometimes uses a semicolon between the listing of SEQ ID NO:X and complementary sequence of SEQ ID NO:X. Appropriate correction is required for uniformity.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenberg et al (WO01/35317, published 17May2001).

The instant claims are drawn to "An isolated nucleic acid comprising ≥ 12 , or ≥ 15 , or ≥ 18 consecutive nucleotides of a nucleotide sequence selected from the group consisting of SEQ ID Nos:1-18, or complementary sequences of SEQ ID NO:1-18."

The open phrase "comprising" permits a scope of any length of isolated nucleic acid which at a minimum has either 12, 15, or 18 consecutive nucleotides of SEQ ID NO:1-18.

Eisenberg et al teach the claimed isolated nucleic acid comprising all of SEQ ID NOs:1, 2, (page 55; SEQ ID NO:12).

9. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gicquel et al (WO 99/09186, published 25February1999).

The instant claims are drawn to "An isolated nucleic acid comprising ≥ 12 , or ≥ 15 , or ≥ 18 consecutive nucleotides of a nucleotide sequence selected from the group consisting of SEQ ID Nos:1-18, or complementary sequences of SEQ ID NO:1-18."

The open phrase "comprising" permits a scope of any length of isolated nucleic acid which at a minimum has either 12, 15, or 18 consecutive nucleotides of SEQ ID NO:1-18.

Gicquel et al teach the claimed isolated nucleic acid comprising all of SEQ ID NOs:3, 4 (Figure 1C'; SEQ ID NO:1C'; SEQ ID NO:33).

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10. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al (WO 01/02568, published 11 January 2001).

The instant claims are drawn to "An isolated nucleic acid comprising ≥ 12 , or ≥ 15 , or ≥ 18 consecutive nucleotides of a nucleotide sequence selected from the group consisting of SEQ ID Nos:1-18, or complementary sequences of SEQ ID NO:1-18."

The open phrase "comprising" permits a scope of any length of isolated nucleic acid which at a minimum has either 12, 15, or 18 consecutive nucleotides of SEQ ID NO:1-18.

Williams et al teach the claimed isolated nucleic acid comprising all of SEQ ID NOs:6 (Page 827-828).

11. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Menozzi et al (WO 97/44463, published 27 November 1997).

The instant claims are drawn to "An isolated nucleic acid comprising ≥ 12 , or ≥ 15 , or ≥ 18 consecutive nucleotides of a nucleotide sequence selected from the group consisting of SEQ ID Nos:1-18, or complementary sequences of SEQ ID NO:1-18."

The open phrase "comprising" permits a scope of any length of isolated nucleic acid which at a minimum has either 12, 15, or 18 consecutive nucleotides of SEQ ID NO:1-18.

Menozzi et al teach the claimed isolated nucleic acid comprising all of SEQ ID NOs:7, 8 (Figure 10).

12. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischmann et al (U.S. Pat. No. 6,294,328, 25 September 2001).

The instant claims are drawn to "An isolated nucleic acid comprising ≥ 12 , or ≥ 15 , or ≥ 18 consecutive nucleotides of a nucleotide sequence selected from the group consisting of SEQ ID Nos:1-18, or complementary sequences of SEQ ID NO:1-18."

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The open phrase "comprising" permits a scope of any length of isolated nucleic acid which at a minimum has either 12, 15, or 18 consecutive nucleotides of SEQ ID NO:1-18.

Fleischmann et al teach the claimed isolated nucleic acid comprising all of SEQ ID NOs:12 (SEQ ID NO:1).

13. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nano et al (U.S. Pat. No. 6,228,371, 8May2001).

The instant claims are drawn to "An isolated nucleic acid comprising ≥ 12 , or ≥ 15 , or ≥ 18 consecutive nucleotides of a nucleotide sequence selected from the group consisting of SEQ ID Nos:1-18, or complementary sequences of SEQ ID NO:1-18."

The open phrase "comprising" permits a scope of any length of isolated nucleic acid which at a minimum has either 12, 15, or 18 consecutive nucleotides of SEQ ID NO:1-18.

Nano et al teach the claimed isolated nucleic acid comprising all of SEQ ID NOs:15 and 16 (SEQ ID NO:75) and procedures utilizing said sequence (col 15, line 8 to col. 17, line 17).

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 7 depends from claim 6 and recites "wherein a member of said pair comprises an observable marker." However, claim 6 recites "said pair being selected from the group consisting of SEQ ID NO:X and SEQ ID NO:Y", but does not recite that either member of the pair "comprises" anything extra. It is recommended that claim 7 recites "wherein a member of said pair further comprises an observable marker."

Claims 8 and 9 depend from claim 7, but does not correct the indefiniteness.

17. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 appears to be identical to claim 6. Claim 10 recites "The pair of forward and reverse primers of claim 6 as PCR primers in the detection of a *Mycobacterium tuberculosis* species." The phrase "as PCR primers in the detection of a *Mycobacterium tuberculosis* species" is intended use and as such does not impart any patentable criticalities. Clarification is required if the product of claim 10 is to be structurally different from the product of claim 6.

Conclusion

18. Claims 1-5 and 7-10 are rejected. Claim 6 is allowable.

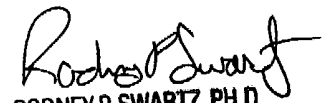
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

August 23, 2004